Exhibit 11

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HYPERBRANCH MEDICAL TECHNOLOGY, INC.

Petitioner

v.

INCEPT LLC

Patent Owner

Case No: IPR2016-01836

Patent No.: 7,009,034

PATENT OWNER'S MOTION TO SUBMIT SUPPLEMENTAL INFORMATION UNDER 37 C.F.R. § 42.123(b)

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A. Introduction

Patent Owner hereby moves for leave to submit Wallace U.S. Patent 6,312,725 ("Wallace"), which was deliberately withheld by Petitioner and which demonstrates that the hydrogels of the primary Rhee '500 and Rhee '587 references failed biocompatibility tests by producing a "severe foreign body response" and "thick encapsulation of the hydrogel and abscess formation." The Rhee hydrogels would not have been selected by one of skill for modification because they were known to be unsuitable for coating a tissue of a patient. Wallace directly refutes Petitioner's *prima facie* case of obviousness of the claims for which trial has been instituted. Patent Owner also seeks to submit a supporting expert declaration.

B. Wallace Refutes Petitioner's *Prima Facie* Case of Obviousness Based on the Tetra-amino PEG Hydrogels of the Primary References.

Wallace issued November 6, 2001 from an application filed on April 16, 1999. Wallace shows knowledge in the art at the time of invention with respect to the hydrogels disclosed in Rhee '500 and Rhee '587. Claim 1 of the '034 patent requires that the claimed composition be suitable to coat a tissue of a patient. Each of Rhee '500 and Rhee '587 teaches the aim of making compositions that, at the very least, are not inflammatory and not immunogenic. See Ex. 1004 at 3:28-35.

However, neither Rhee '500 nor Rhee '587 provided any test data for the inflammatory or immunogenic effects of its hydrogels, but only this aim. The lead inventor on Rhee '500 and Rhee '587, Woonza M. Rhee, is a co-inventor on

Wallace; and another individual, Jacqueline A. Schroeder, is a co-inventor on Rhee '587 and Wallace. Wallace, filed shortly after Rhee '500 issued, actually tested biocompatibility in white rabbits and reports "a severe response to hydrogels made with amino PEG" including a "severe foreign body response" and "thick encapsulation of the hydrogel and abscess formation." Wallace at 13:38-41.

Petitioner's expert Dr. Lowman relies heavily—if not exclusively—on the tetra-amino PEG hydrogels described in Rhee in arguing *prima facie* unpatentability. See Ex. 1041 at ¶ 37 ("*Critically*, the hydrogel composition of Example 6 of Rhee '500 has a tetra-functional electrophile and a tetrafunctional nucleophile—i.e., both precursors have four reactive functional groups per molecule. That is, there are a large number of reactive functional groups on each precursor, such that they more readily achieve a crosslinked three-dimensional network") (emphasis added).

Petitioner focuses on the tetra-amino PEG hydrogels while relying solely on Rhee's then-untested aim of making hydrogels that are biocompatible, non-immunogenic, non-toxic, and non-inflammatory, and entirely ignores the existing knowledge in the art, as demonstrated by Wallace, that these same hydrogels caused a "severe foreign body response" and "thick encapsulation of the hydrogel and abscess formation" during *in vivo* testing.

Evidence tending to show that a POSA would not have combined references as proposed, is relevant to the issue of obviousness. M.P.E.P. § 2145; *Crocs, Inc. v. U.S. Int'l Trade Comm'n,* 598 F.3d 1294 (Fed. Cir. 2010). Rhee '500 and Rhee '587 cannot form the basis of *prima facie* obviousness because, as taught by Wallace, the Rhee hydrogels would not have been selected as a lead hydrogel for modification based on their known "severe foreign body response" and "thick encapsulation of the hydrogel and abscess formation." See *Procter & Gamble Co. v. Teva Pharms. USA, Inc.,* 566 F.3d 989 (Fed. Cir. 2009) ("An obviousness argument based on structural similarity between claimed and prior art compounds 'clearly depends on a preliminary finding that one of ordinary skill in the art would have selected [the prior art compound] as a lead compound.'"); *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*, 678 F.3d 1280 (Fed. Cir. 2012) ("the analysis is guided by evidence of the compound's pertinent properties . . . [and] adverse effects such as toxicity"); *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.,* 492 F.3d 1350 (Fed. Cir. 2007) ("Significantly, the closest prior art compound . . . exhibited negative properties that would have directed one of ordinary skill in the art away from the compound."). For these reasons, Wallace shows that a POSA would not have selected Rhee '500 or Rhee '587 as a lead hydrogel for combination with Bass or Tse as proposed by Petitioner but, rather, would have looked elsewhere to hydrogels that are more biocompatible.

C. The Supplemental Information *Reasonably* Could Not Have Been Obtained Earlier.

Patent Owner acknowledges that Wallace was of record in the '034 Patent. However, Patent Owner was unaware that Rhee and her colleagues later reported that the hydrogels disclosed in Rhee '500 and Rhee '587 failed biocompatibility testing, and Patent Owner certainly had no reason to look to Wallace in search of such information.

It was not until late September 2017 after Hyperbranch served its opening expert report on invalidity in the parallel district court litigation that Patent Owner first appreciated the relevance of Wallace to the present IPR. Ex. 2009 at ¶ 5. Patent Owner promptly contacted opposing counsel to discuss the matter (Ex. 2011) and, immediately after this discussion took place, contacted the Board to request a conference call to discuss the present motion (Ex. 2012).

D. It Is in the Interests-of-Justice to Allow Patent Owner to Address Wallace at this Stage to Cure a Discovery Violation By Petitioner.

Petitioner was aware of Wallace at least as early as November 2016, when Hyperbranch cited Wallace in its invalidity contentions in the district court litigation. Ex. 2009 at ¶¶ 2-4; Ex. 2010 at 23 and 28. In its September 2017 opening expert report on invalidity, Hyperbranch characterized the disclosure of Wallace in great detail including how it was considered to anticipate claims of another patent involved in the district court action. *Id*. at ¶ 5.

Despite Wallace having been known to Petitioner at least as early as November 2016, Wallace was not produced to Patent Owner under the discovery provisions of 37 C.F.R. § 42.51(b)(1)(iii), which required its production. Given Hyperbranch's prominent use of Wallace in its September 2017 opening expert report on invalidity, there is no doubt that the substance of Wallace was known to Petitioner no later than the time its reply was filed in the present IPR.

There would be no prejudice to Petitioner in allowing Patent Owner to file the exhibit and supporting declaration as requested herein, as Petitioner prepared its reply and expert declaration with full knowledge of Wallace. Patent Owner would be severely prejudiced if not allowed to make Wallace of record with a supporting supplemental declaration, given Wallace's highly relevant disclosure. Such a declaration has already been served on Petitioner in the parallel district court litigation, to which Petitioner has responded. Relief to the Patent Owner would serve the interests-of-justice and is an appropriate remedy to cure the above-described discovery violation on the part of Petitioner.

E. Conclusion

For the foregoing reasons, Patent Owner requests leave to submit Wallace as an exhibit along with a supporting declaration explaining its relevance to the claims for which trial has been instituted.

Respectfully submitted,

Dated: October 24, 2017

/Paul M. Rivard/

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CERTIFICATE OF SERVICE

The undersigned certifies service on the Petitioner, pursuant to 37 C.F.R. § 42.6(e) and agreement of counsel, by electronic (e-mail) delivery of a true copy of the foregoing PATENT OWNER'S MOTION TO SUBMIT SUPPLEMENTAL INFORMATION UNDER 37 C.F.R. § 42.123(b), to counsel of record for Petitioner as follows:

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Exhibit 12

ANTHONY LOWMAN, Ph.D.

ROUGH DRAFT - UNCERTIFIED

This transcript is an UNCERTIFIED ROUGH DRAFT TRANSCRIPT. It contains raw output from the court reporter's stenotype machine translated into English by the court reporter's computer, without the benefit of proofreading. It will contain untranslated steno outlines, mistranslations (wrong words), and misspellings. These and any other errors will be corrected in the final transcript. Since this rough draft transcript has not been proofread, the court reporter cannot assume responsibility for any errors therein. This rough draft transcript is intended to assist attorneys in their case preparation and is not to be construed as the final transcript. It is not to be read by the witness or quoted in any pleading or for any other purpose and may not be filed with any court.

Q. Well, let me ask you this, did you review Dr. May's reply report in this case?

MR. PIVOVAR: Just so we're clear, do you want him to keep reviewing?

MR. SHULL: I'm going to ask him a question first.

MR. PIVOVAR: Okay.

BY MR. SHULL:

Q. Did you review Dr. May's reply report in this case?

A. Yes, I did review his report.

Q. Did you review his reply report before you -- before today obviously?

A. Well, yes. I think I wrote a rebuttal --

Q. Did you review --

MR. PIVOVAR: Wait, wait, wait. Wait, wait. I think that answer -- so look at --

MR. SHULL: I didn't mean to interrupt you. I apologize.

MR. PIVOVAR: No, but it wasn't really that, it's -- just look at what he said about that. I think you need to clarify the question back to him. I don't want to get in your way.

MR. SHEULL: So...

MR. PIVOVAR: He said he wrote a rebuttal and I think you're asking about the --

MR. SHULL: Gotcha. Gotcha.

BY MR. SHULL:

Q. So you understand there's the opening report, there's the rebuttal report, and then there's the reply report, correct? So the reply report that I'm referring to is actually Dr. May's third report --

A. Oh.

Q. -- in the order of the three. And my question is did you review Dr. May's reply report, which is the third report, before your deposition today?

A. His reply report, when -- which document was that? When was it written? There were a number of reports.

Q. That would have been three weeks ago probably.

A. So would it have been the same day as my reply report?

Q. That's correct.

A. So I've had -- I've seen it, not in depth. Quite honestly, when these reports were submitted

and sent I was in the middle of a two-week trip to China.

Q. Fair enough.

A. So I've had limited time to review it.

Q. So -- okay. So this was an exhibit to Dr. May's reply report. So you can continue to review it.

A. Okay.

Q. And then let me know when you're done reviewing it.

(Witness reviewing document.)

BY MR. SHULL:

Q. Dr. Lowman, can I ask you what page you are on in the document so far?

A. 21.

Q. And page 21 is past page 9 that we were talking about earlier, correct?

A. Yes.

Q. Do you think you need to continue reading the document in order to answer my questions that were related to page 9?

MR. PIVOVAR: Object to form.

BY THE WITNESS:

A. Well, I don't know what's in the remainder

of the document.

Q. Okay. So in order to answer my questions that I was asking on page 9 of the document you think you need to review this entire document?

MR. PIVOVAR: Object to form.

BY THE WITNESS:

A. Well, I don't know if there's any context missing in the document.

Q. Okay. So I'm going to go back and ask my question because obviously we have a limited amount of time during the deposition today.

A. Okay.

Q. And if you can't answer it without reading the entire document just say so and we'll move on.

A. Okay.

Q. Fair enough?

A. Okay.

Q. So when -- on page 9 of Plaintiff's Exhibit 292 --

A. Uh-huh.

Q. -- where it states that -- where it states that "After the mix formulation comes in contact with the tissue the PEG -- or the PEG and the PEI components cross-link to form an inner penetrating

Q. Did you see it referenced or listed among the materials that you considered in preparing your reports?

(Witness reviewing document.)

BY THE WITNESS:

A. I don't see it, but I'm wondering if I'm missing something. It has some familiarity, but sitting here I'm not --

Q. Okay. So you've reviewed the list of materials that are included in your three reports in this case, correct?

A. Yes, but I might have -- I might have missed it as I went through there.

Q. Well, I didn't see it either.

A. Okay.

Q. So sitting here today, do you remember reviewing this patent application in preparing your opinion?

A. I shouldn't speculate. I don't know -- I don't know if I reviewed this or not, to be honest.

Q. Fair enough.

A. There's some familiarity, but there's so little information on here other than a number it's hard to get a cue.

Q. I understand.

Can you refer to paragraphs 213 and 214 of your reply report.

A. Okay. I'm here.

Q. Let me know when you're there.

A. Okay. I'm there.

Q. 213 and 214 appear to be duplicative and I wanted to know if that was purposeful or if there was something missing that I'm not seeing?

A. This is my reply report. I was filed on the 13th. I was in China. So this would have been filed at 3:00 in the morning. So I might have missed --

Q. Fair enough.

A. -- a duplicative paragraph.

Q. I understand.

Have you ever heard the term foamed hydrogels or foamed gels?

A. Yes.

Q. What does that mean to you?

A. I mean, it could mean a lot of things to different people. I don't want to speculate a meaning if someone else was using a hydrogel a different way than I was. So...

Q. Sure. Well, you've heard of the term "foam gels" being used before in your experience, right?

A. Yeah. I've used -- I've used a foam, sure.

Q. And those foam gels, do they have -- would you consider them to be a porous structure?

MR. PIVOVAR: Object to form.

BY THE WITNESS:

A. In some cases.

Q. And in those -- in those cases where you have found them to have a porous structure, did they have micro bubbles?

MR. PIVOVAR: Object to form.

BY THE WITNESS:

A. The ones I've worked with foam gels that were made not with microbubbles, no. So I would use different types.

Q. Have you ever seen a foam gel or foamed hydrogel that did not have microbubbles?

MR. PIVOVAR: Object to form.

BY THE WITNESS:

A. Well, are you talking about -- what -- what type of bubble are we talking about, how about that?

Q. Any kind of bubble.

A. Air bubble? Liquid bubble?

Q. Air bubble.

A. Yeah, I've seen plenty of foam gels without air bubbles.

Q. Okay. How about foam gels without liquid bubbles?

A. I don't know if I'd call them -- it doesn't have to be necessarily liquid. I mean, it could be a -- there are some two-phase gels that have some solid bubbles, but yeah, that's quasi solid. You could have a gel bubble within a gel.

Q. Sure. In order to be a foamed gel or a foamed hydrogel doesn't it have to have some sort of bubbles in it?

MR. PIVOVAR: Object to form.

BY THE WITNESS:

A. I would think it has to have two -- two phases.

Q. What do you mean by that?

A. You'd have two phases. You'd have one hydrogel phase within a second -- you'd have one phase within -- dispersed within a hydrogel phase, if that's what we're talking about, a foam gel. I've seen cases where you -- people have done air bubbles, I've personally done work where it's been a

of the claimed and disclosed inventions"; do you see that?
A. Yes.
Q. And what did you mean by that statement?
(Witness reviewing document.)
BY THE WITNESS:
A. I think I mean exactly what it says. It's biocompatible cross-linked polymers are fundamental to the application.
Q. At paragraph 24 of your reply report you mention the IPR proceeding and state that the Wallace patent was not part of the IPR proceeding; do you see that?
MR. PIVOVAR: Object to form.
BY THE WITNESS:
A. I don't see anything in paragraph 24.
Q. I might be in the wrong paragraph. Let me look. Well, paragraph 24 and 25 mention the IPR proceeding, right?
THE WITNESS: Can I take a one-second break off the record to stretch my neck.
MR. SHULL: Sure. Absolutely.
THE VIDEOGRAPHER: We are going off the record at 4:24.

(A short break was had.)
THE VIDEOGRAPHER: We are back on record at 4:25.
BY MR. SHULL:
Q. So paragraphs 24 and 25 of your reply report reference the IPR proceeding, right?
A. Yes.
Q. And it makes reference to Dr. Mays's contention about the Rhee 500 hydrogels not being biocompatible; do you see that?
A. I see that -- I guess are you pointing to a specific comment?
Q. Not yet. Not yet, but I'm just making you refer -- I'm referring you to the portion of the paragraph where you're actually referencing Dr. Mays's contention that the Rhee 500 hydrogels are not biocompatible. I think you say that in the second sentence in paragraph 25. Do you see that?
A. I say "During that deposition Dr. Mays never once asserted that the Rhee 500 hydrogels were not biocompatible as they does in his rebuttal report in this litigation proceeding."
Q. Sure. And the deposition you're referring to is the IPR proceeding?

A. Yes.
Q. And you read Dr. Mays's rebuttal report where he makes that contention with respect to the Rhee 500 hydrogel?
A. I read Dr. Mays's report -- yeah, I've read his rebuttal report. Is it the rebuttal report?
Q. Rebuttal.
A. Rebuttal report where he speaks about --
Q. And you understand that Dr. Mays's contention is based on what he understands Wallace to be disclosing?
A. Yeah. I mean, the biocompatibility was kind of a new issue Dr. Mays has disclosed. So again, I think I first saw it when I was in China. So I've spent not as much time as I would like, but my thought is that some of this, -- yes, some of it comes from his interpretation of Wallace.
Q. Why didn't you rely so Wallace for your positions that you've taken in the IPR proceeding?
MR. PIVOVAR: Object to form.
BY THE WITNESS:
A. Honestly, I'm not -- I sitting right here today I'm only worried about what I've got in these reports, which as you see is quite voluminous. It's

almost a thousand pages of documents I'm trying to discuss. I really can't tell you my thoughts on the IPR proceedings right now.
Q. Sure.
A. I think we're going to be able to do that in a couple weeks if I understand the schedule correctly.
Q. Sitting here today, can you think of any material differences between the hydrogels that are disclosed in the Rhee '500 Patent and the hydrogels that are disclosed in the Wallace patent?
MR. PIVOVAR: Object to form.
BY THE WITNESS:
A. Well, I can put -- I'd have to put both in front of me and take a look at them if you'd like.
Q. At paragraph 75 of your reply report you explain that you used a different method to determine gel time than the Rhee '500 Patent; do you see that?
MR. PIVOVAR: Object to form.
BY THE WITNESS:
A. Yeah. I talk about -- I talk about the differences -- actually, I'm basically rebutting Dr. Mays's assertion about my gel time experiments,